

**§ 882.4650 Neurosurgical suture needle.**

(a) *Identification.* A neurosurgical suture needle is a needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.

(b) *Classification.* Class I. If the device is made of the same material (single, surgical-grade, stainless steel alloy) that was used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 54 FR 25051, June 12, 1989]

**§ 882.4700 Cottonoid paddie.**

(a) *Identification.* A cottonoid paddie is a cotton pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

(b) *Classification.* Class II (performance standards).

**§ 882.4725 Radiofrequency lesion probe.**

(a) *Identification.* A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.

(b) *Classification.* Class II (performance standards).

**§ 882.4750 Skull punch.**

(a) *Identification.* A skull punch is a device used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.

(b) *Classification.* Class I (general controls).

**§ 882.4800 Self-retaining retractor for neurosurgery.**

(a) *Identification.* A self-retaining retractor for neurosurgery is a self-locking device used to hold the edges of a wound open during neurosurgery.

(b) *Classification.* Class II (performance standards).

**§ 882.4840 Manual rongeur.**

(a) *Identification.* A manual rongeur is a manually operated instrument used for cutting or biting bone during sur-

gery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

**§ 882.4845 Powered rongeur.**

(a) *Identification.* A powered rongeur is a powered instrument used for cutting or biting bone during surgery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

**§ 882.4900 Skullplate screwdriver.**

(a) *Identification.* A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patient's skull by screws.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994]

## Subpart F—Neurological Therapeutic Devices

**§ 882.5030 Methyl methacrylate for aneurysmorrhaphy.**

(a) *Identification.* Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or obliteration by aneurysm clip.

(b) *Classification.* Class II (performance standards).

**§ 882.5050 Biofeedback device.**

(a) *Identification.* A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.

(b) *Classification.* Class II (performance standards).